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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/588,094	FERRANTE ET AL.
	Examiner	Art Unit
	YATE' K. CUTLIFF	1622

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 19* is/are pending in the application.

4a) Of the above claim(s) *7 - 11, 13 - 17 & 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6, 12 & 18* is/are rejected.

7)☒ Claim(s) *1 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-18, and election of the species vascular or immunological disorders, in particular cardiovascular disease as the condition being treated and the species ß-oxa-23:4n-6 (MP3) as the compound being administered in the reply filed on June 3, 2011is acknowledged. The traversal is on the ground(s) that the claimed subject matter is linked to from a single general inventive concept because both Groups I and II relate to the compound of Formula I. This is not found persuasive because as set forth in the Requirement for restriction the special technical feature of the compound of Formula (I) is disclosed in Ferrante et al. (WO 96/11908). Additonally, the compound in Ferrante is shown to have pharmaceutical applications. Furthermore, PCT/GL/ISPE/1 Prov.2, Chapter 10, 10.2 states:

> 10.03 Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

Based on Applicant's election, the elected invention for search and examination purposed is the method for the treatment of cardiovascular disease by administering a compound of ß-oxa-23:4n-6 (MP3).

Claim 19 is withdrawn from consideration as being drawing to a non-elected invention.

Claims 7 – 11 and 13 - 17 are withdrawn from consideration as being drawn to non-elected species.

Claims 1 - 6, 12 and 18 are under examination at it relates to the species vascular or immunological disorders, in particular cardiovascular disease as the condition being treated and the species ß-oxa-23:4n-6 (MP3).

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to because figures 1, 15 and 17 are not in compliance with the requirement of 37 CFR 1.121(d). The lettering in figure 1 is objected to for not being at least .32 cm (1/8 inch). The structure in figure 15 appears to form ringed compounds. The lettering in figure 17 is objected to for not being at least .32 cm (1/8 inch). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted

after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

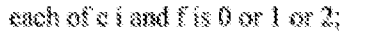
Specification

3. The disclosure is objected to because of the following informalities: there are compounds on pages 28 – 31 that appear to be ringed structures, when they are actually chain structures.

Appropriate correction is required.

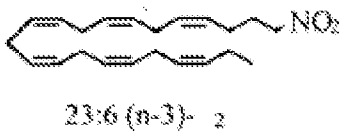
Claim Objections

4. Claims 1 and 12 are objected to because of the following informalities: claim 1 is missing a comma in the following:



and

missing a period after the following:



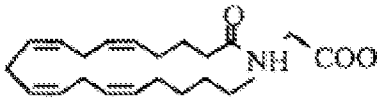
, on page 16 of the claims.

Appropriate correction is required.

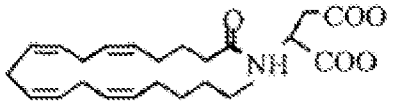
5. Claim 12 is objected to because many of the compound structures are missing the proton (H+).

Appropriate correction is required.

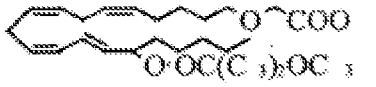
6. Claim 12 is objected to because the compound structures as drawn infer ring structures, for example;



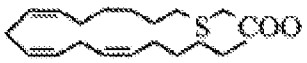
20:4n-6 Gly (PT1)



20:4n-6 Asp (PT2)

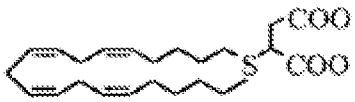


15-OOC(C)OC -β-oxa 23:4n-6

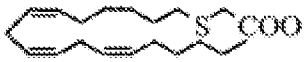


β-thia-21:3n-6

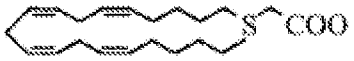
β-thia-23:4n-6



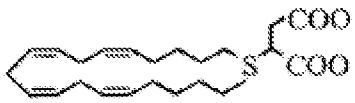
α- β-thia-23:4n-6



β-thia-21:3n-6



β-thia-23:4n-6



α- β-thia-23:4n-6

The above listing does not include all instances of this error. Applicant should review the claims and specification to correct such errors.

Claim Rejections - 35 USC § 112 (Written Description)

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 – 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

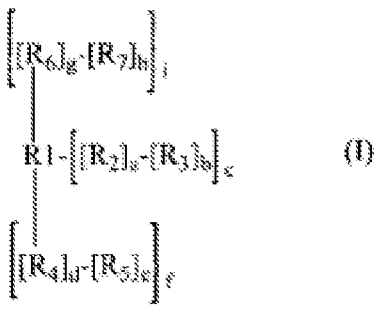
The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (ie. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has

demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such comparison.

I. Scope of claims (based on elected subject matter)

In the instant case: claim 1 is broadly drawn to a method for treatment or prophylaxis of a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain in a subject said method comprising administering to said subject an effective amount of a compound having the structure of Formula (I):



(I)

Wherein the scope of the variables for R2 – R7 are broader than supportd by the disclosure for the treatement or prophylxis of the listed conditions. The scope of the compounds of formula (I) that are congrurent with the disclosure for tratment of some of the conditions claimed are set out on pages 28 - 31 of the spefication. The elected compound ß-oxa-23:4n-6 (MP3) for treatment of cardiovascular disease is congruent with the scope of the disclosure.

II. Scope of disclosure

Reduction to Practice:

The disclosure teaches the following:

20:4n-6 ASP (PT2) for treating pain (Example 5);

(Lx1), (Lx2), (Lx3), (Lx4), (Lx5), (Lx7), (Lx8) and (Lx9) have some inhibition of PKC activation. (see page 31 and Example 7);

(MP3) ß-oxa-23:4n-6 inhibits the IκB kinase – NFκB signing pathway (Examples 8 – 10);

(MP3) ß-oxa-23:4n-6 has anti-atherosclerotic effect (Example 11); and

(MP5) ß-oxa-21:3n-3 prevents agonist-stimulated association of PKCß (Example 12 - 15).

Reduction to Structural or Chemical Formulas:

The only disclosure, in addition to the species reduced to practice as described above and those compounds set out on pages 28 – 31 of the Specification, is in form of a *list* of possible substituents for each variable. This type of disclosure is not viewed to be a representation of any of the species it entails. A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin,* 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 fled. Cir. !996). Therefore, there is no disclosure of species (eg. by reduction to structural/chemical formulas) in addition to those reduced to practice.

Correlation between Structure and Function:

A correlation between Structure and function, for the instantly claimed genus of compounds, other than the elected species and those used in the Examples, is neither known in the art nor disclosed in the specification. Thus, it is not understood what *specific structural elements* are *essential* for the activity of

the instantly claimed compounds for treatment or prophylaxis of a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain in a subject .

Applicant's compound of Formula (I) is so broad that it encompasses polyunsaturated fatty acids (PUFA) as well as long chain alkanes, alkenes and every know fatty acid. For example the compound of formula (I) can be decane, hexacosanoic acid or any omega-3 PUFA.

Decane is known to be harmful if swallowed and affects the central nervous system. (see Regents, Inc., 2003). Hexacosanoic acid is known to be associated with atherosclerosis and metabolic syndrome (see Cayman Chemical Company, 2011). Also, high levels of hexacosanoate in erythrocyte membranes are shown to be closely related to atherosclerosis. (Antoku, Atherosclerosis, 2000). Furthermore, according to Metametrix low dietary omega-3 PUFAs can lead to increased inflammatory response, while excessive or unbalanced supplementation of omega-3 PUFA's can suppress immune function. (see page 3, Omega-3 Dominance).

The disclosure does not show that the Applicant provided screening *in vitro* and *in vivo* for the full scope of the compounds of Formula (I) to determine which compounds would exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). The Applicant has failed to describe any *in vitro* and *in vivo* screening of any

representative number of patients suffering conditions associated with a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain; for the full scope of compounds of formula (I).

The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833,166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Level of skill and knowledge in the art:

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an Ph.D. in a scientific discipline such as organic synthetic chemistry, polymer chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like. Due to the unpredictability in the pharmaceutical art based on the cited references; it is noted that the long chain alkanes, long chain alkenes, fatty acids or fatty acid derivatives, would is require individual assessment for physiological activity by in vitro and in vivo screening to determine if the desired pharmacologically activity is achieved with claimed conditions.

III. Analysis of Fulfillment of Written Description Requirement:

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable

that claim(s) 1 - 6 are broad and generic, with respect to all possible compounds encompassed by the claims and the possible modalities associated with a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus of the compounds and the diseases to be treated with those compounds. While having written description of the process for:

20:4n-6 ASP (PT2) for treating pain (Example 5),

(Lx1), (Lx2), (Lx3), (Lx4), (Lx5), (Lx7), (Lx8) and (Lx9) have some inhibition of PKC activation. (see page 31 and Example 7),

(MP3) ß-oxa-23:4n-6 inhibits the IκB kinase – NFκB signing pathway (Examples 8 – 10),

(MP3) ß-oxa-23:4n-6 has anti-atherosclerotic effect (Example 11), and

(MP5) ß-oxa-21:3n-3 prevents agonist-stimulated association of PKCß (Example 12 - 15); the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims, and use of those compounds to teat any all types of conditions associated with a NFκB related or associated condition, a PKCß related or associated condition, vascular or

immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 112 (Enablement)

9. Claims 1- 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment of cardiovascular disease with ß-oxa-23:4n-6 (MP3), does not reasonably provide enablement for prophylaxis of cardiovascular disease, or the treatment or prophylaxis of a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain with the full scope of the compounds of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

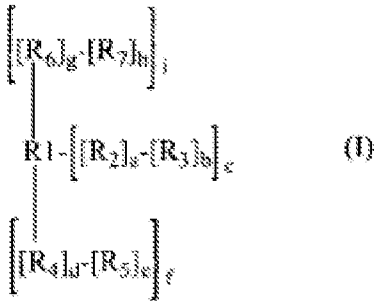
The test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (United States v. Telectronice, 8, USPQ2D 1217 (Fed. Cir, 1988). Whether undue experimentation is needed is not based upon a single factor but rather in a conclusion reached by weighing many factors. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the scope of the claims:

The nature of the claims are drawn to a method for treatment or prophylaxis of a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease

and pain in a subject said method comprising administering to said subject an effective amount of a compound having the structure of Formula (I):



(I)

The scope of the invention in the claims includes the treatment or prophylaxis of the claimed conditions, wherein scope of the variables for R2 – R7 are broader than supportd by the disclosure for the treatement or prophylxis of the listed conditions; and include polyunsaturated fatty acids (PUFA) as well as long chain alkanes, alkenes and every know fatty acid. For example the compound of formula (I) can be decane, hexacosanoic acid or any omega-3 PUFA.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the prior art is that decane is known to be harmful if swallowed and affects the central nervous system. (see Regents, Inc., 2003). Hexacosanoic acid is known to be associated with atherosclerosis and metabolic syndrome (see Cayman Chemical Company, 2011). Also, high levels of hexacosanoate in erythrocyte membranes are shown to be closely related to atherosclerosis. (Antoku, Atherosclerosis, 2000). Furthermore, according to Metametrix low dietary omega-3 PUFAs can lead to increased inflammatory

response, while excessive or unbalanced supplementation of omega-3 PUFA's can suppress immune function. (see page 3, Omega-3 Dominance).

Also, with regard to whether omega-3 fatty acids can protect against coronary heart disease, Din teaches that omega-3 fatty acids from fish and fish oil can protect against coronary heart disease. However, Din discloses that several areas of uncertainty remain; the optimal intake of omega-3 fatty acids and the mechanism of action. (see page 30 col. 1 para. 1 & 2). Further, Din states that the precise effects of omega-3 fatty acids on the fundamental cellular processes and their potential impact on coronary heart disease are yet to be delineated completely. (see page 33, col. 2 para. 1).

Additionally, the state of the prior art involves pharmacology and general chemistry. These technological areas, especially, pharmacology, involve *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases/conditions by a certain mechanism). Thus, there is no absolute predictability even in view of the seemingly high level of skill in the art. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would not necessarily recognize, with regards to therapeutic effects, whether or not the full scope of the compound of formula (I) would successfully treat or

prophylaxis of a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain.

(5) The relative skill of those in the art:

The relative skill in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for:

20:4n-6 ASP (PT2) for treating pain (Example 5),

(Lx1), (Lx2), (Lx3), (Lx4), (Lx5), (Lx7), (Lx8) and (Lx9) have some inhibition of PKC activation. (see page 31 and Example 7),

(MP3) ß-oxa-23:4n-6 inhibits the IκB kinase – NFκB signing pathway (Examples 8 – 10),

(MP3) ß-oxa-23:4n-6 has anti-atherosclerotic effect (Example 11), and

(MP5) ß-oxa-21:3n-3 prevents agonist-stimulated association of PKCß (Example 12 - 15).

However, the specification does not provide guidance for all long chain alkanes (C9 – C26), alkenes (C9 - C26) and every know fatty acid, for treating and prophylaxis of a condition selected from a NFκB related or associated condition, a PKCß related or associated condition, vascular or immunological conditions such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain.

(8) The quantity of experimentation necessary:

In view of the complexity of issues outlined above and the absence of in vivo data, the specification does not enable one of ordinary skill in the art to practice the invention of claims 1 - 6 without undue experimentation.

To emphasize this point the Examiner points Applicants to "Genentech, 108 F.3d at 1366 and *Brenner v. Manson,* 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)" which states,

> "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

10. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 18 recites the broad recitation cardiovascular disease, and the claim also recites strokes and any condition of systemic vasculature and includes atherosclerosis, chronic heart failure and general heart disease" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 1- 6, 12 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Berg (US 2002/0198259), Berge (US 6,046,237) and Berge (US 5,093,365).

14. The rejected claim covers a method for the treatment or prophylaxis of cardiovascular disease by administering to a subject an effective amount of a compound having the structure of ß-oxa-23:4n-6 (MP3). Dependent claims 4, 5, 6 and 12 disclose the claimed species of the compound of Formula (I). Dependent claim 18 discloses the cardiovascular disease includes atherosclerosis, chronic heart failure and general heart disease.

15. Berg discloses the below compound for treatment of coronary heart disease.

sis.

[0030] We have also shown that the compounds of the present invention reduces the proliferation and mobilisation of smooth muscle cells, and it is known that proliferation of smooth muscle cells is a pathological factor in diseases such as atherosclerosis, coronary heart disease, thrombosis, myocardial infarction, stroke and smooth muscle cell neoplasms, and the treatment and/or prevention of such diseases by the use of the compounds of formula (I) are also part of the present invention.

[0031] The present invention relates to the use of fatty acid analogues of the general formula (I):

$CH_3—[CH_2]_m—[X_i—CH_2]_n—COOR$

[0032] wherein n is an integer from 1 to 12, and

[0033] wherein m is an integer from 0 to 23, and

[0034] wherein i is an odd number which indicates the position relative to COOR, and

[0035] wherein X_i independent of each other are selected from the group comprising O, S, SO, SO_2, Se and CH_2, and

[0036] wherein R represents hydrogen or C_1-C_4 alkyl,

[0037] with the proviso that at least one of the X_i is not CH_2,

Further, Berge states that the methods for synthesis of the compound of his formula (I) is described in WO 97/03663, which corresponds to US 6,046,237; wherein US 6,046,237 (‘237) incorporates the process of US 5,093,365 which teaches the process for making the compound of '237, as set out below at column 2.

The compounds according to the present application where X is an oxygen or a sulphur atom may be prepared according to the following general procedure:

16. Claims 1-6, 12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Berge (US 5,093,365) (Berge '365).

17. The claims are described in paragraph 11 above.

18. Berge '365 describes a compound at column 1 lines 55 – 64 that has the effect of reducing the concentration of cholesterol and triglycerides in the blood of mammals. Berge '365 states that excess lipids in blood has been shown to accelerate the development of arteriosclerosis and is a risk factor for myocardial infraction. Also, that a reduction of the concentration of lipids in the blood by diet or drugs is used as a preventive measure in people at risk due to high blood levels of cholesterol and triglycerides.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew D. Kosar can be reached on (571) 272 -0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YATE' K. CUTLIFF/
Examiner, Art Unit 1622